

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

NEW ENGLAND CARPENTERS HEALTH  
BENEFITS FUND, PIRELLI ARMSTRONG  
RETIREE MEDICAL BENEFITS TRUST;  
TEAMSTERS HEALTH & WELFARE FUND  
OF PHILADELPHIA AND VICINITY;  
PHILADELPHIA FEDERATION OF  
TEACHERS HEALTH AND WELFARE  
FUND; DISTRICT COUNCIL 37, AFSCME -  
HEALTH & SECURITY PLAN; JUNE  
SWAN; MAUREEN COWIE and BERNARD  
GORTER,

Plaintiffs,

v.

FIRST DATABANK, INC., a Missouri  
corporation; and McKESSON  
CORPORATION, a Delaware corporation,

Defendants.

C.A. No. 1:05-CV-11148-PBS

**DECLARATION OF STEVE W. BERMAN IN SUPPORT OF PLAINTIFFS' REPLY IN  
SUPPORT OF MOTION FOR LEAVE TO FILE THIRD AMENDED COMPLAINT**

I, Steve W. Berman, hereby declare that:

1. I am a partner of Hagens Berman Sobol Shapiro LLP, resident in its Seattle, Washington, office, and I am one of counsel for the Plaintiffs in the above-captioned matter. I submit this declaration in support of Plaintiffs' Reply in Support of Motion for Leave to File Third Amended Complaint.

2. Attached hereto as Exhibit 1 is a true and correct copy of a McKesson document titled "Academy of Managed Care Pharmacy – A Guide to Understanding Common Prescription Drug Pricing Terms." (MCKAWP 0065863-81.)

3. Attached hereto as Exhibit 2 is a true and correct copy of a third-party document titled "Item File Data Elements – Reimbursement Related Fields." (BR 02151-62) [**FILED UNDER SEAL**].

4. Attached hereto as Exhibit 3 is a true and correct of a third-party document titled "Maximizing Reimbursement and Improving Your Bottom Line." (GM02270-87) [**FILED UNDER SEAL**].

5. Attached hereto as Exhibit 4 is a true and correct copy of a third-party document titled "GeriMed Pro files – Consultant Pharmacist Software." (GM02041-70) [**FILED UNDER SEAL**].

I certify under penalty of perjury that the foregoing is true and correct.

Executed this 1st day of November, 2007.

---

**/s/ Steve W. Berman**  
STEVE W. BERMAN

**CERTIFICATE OF SERVICE**

I hereby certify that a true copy of the above document was served upon the attorney of record for each other party through the Court's electronic filing service on November 1, 2007.

/s/ Steve W. Berman

Steve W. Berman

# Exhibit 1



## *A Guide to Understanding Common Prescription Drug Pricing Terms*

### **Introduction:**

Pharmaceuticals are a valuable and often critical tool in efforts to provide quality health care to patients. Nevertheless, with increasing frequency, serious concerns are being raised as to the high costs of pharmaceuticals and the impact of those high costs on patient access and affordability. Understanding how pharmaceuticals are priced within the product distribution chain can help in assessing the legitimacy of these concerns. Unfortunately, drug pricing terminology is arcane and pricing methodologies are complex.

The distribution chain consists of different levels and includes transactions between manufacturers, wholesalers, retailers and consumers. It may also include other entities serving as intermediaries between these groups. Different terms are used to characterize costs or prices of drugs at the various levels within the distribution chain and in some instances different terms used in describing transactions can refer to the same dollar amount.<sup>1</sup> Terms such as Average Wholesale Price, Best Price and Wholesale Acquisition Cost are commonly used; what they are meant to represent and when and where they are relevant within the distribution chain is not always clear.

### **The Document**

Those outside of the pharmaceutical industry, and even many within it, cannot clearly define the various drug pricing terms. This document was developed by the Academy of Managed Care Pharmacy (AMCP) to assist its members and other interested parties in defining the different drug pricing terms and explaining how and when they are used in the pharmaceutical distribution system.

Within the document, prescription drug price terms are arranged in alphabetical order. Each is defined, its application and use is described, and an explanation of how the price is calculated (if applicable) is provided. An example of a typical drug is shown, followed by several charts that illustrate the drug distribution channel, and the position of each pricing term defined in this paper.

### **About AMCP**

AMCP is a professional association of pharmacists and associates who serve patients and the public through the promotion of wellness and rational drug therapy through the application of managed care principles. The Academy has more than 4,800 members nationally who provide comprehensive coverage and services to over 200 million Americans served by managed care.

<sup>1</sup> Prescription Drug Trends – A Chartbook, The Henry J. Kaiser Family Foundation, Jul 2000.



## *A Guide to Understanding Common Prescription Drug Pricing Terms*

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## *A Guide to Understanding Common Prescription Drug Pricing Terms*

### **Actual Acquisition Cost (AAC)**

#### **Definition:**

AAC is the "retailer's cost to buy drugs (from wholesalers)."<sup>2</sup> This is the final cost of the drug to the pharmacy after all discounts are subtracted. Appendix A (page 12) lists AAC in relation to the Average Wholesale Price (AWP - defined on page 5).

#### **Application:**

Each pharmacy uses AAC to develop their profit/loss financial report. AAC is not generally reported, as it will be different for each pharmacy.

#### **How Calculated:**

AAC can only be calculated by a review of all pharmacy invoices. The federal government uses the Estimated Acquisition Cost (EAC - defined on page 7) as a close approximation of AAC.

#### **Distribution Level:**

Appendix B (page 13) lists the channels of drug distribution. AAC is listed at the "Retailers (Pharmacies)" level.

<sup>2</sup> Prescription Drug Trends - A Chartbook, The Henry J. Kaiser Family Foundation, Jul 2000.



## A Guide to Understanding Common Prescription Drug Pricing Terms

### Average Manufacturer's Price (AMP)

#### Definition:

AMP is "The average price paid to a manufacturer by retail pharmacies or by wholesalers for drugs distributed to the retail pharmac[ies]."<sup>3</sup> AMP is based on sales to the retail sector, which generally pays higher prices than other purchasing sectors. Appendix A (page 12) lists AMP in relation to the Average Wholesale Price (AWP - defined on page 5). Appendix F (page 19) also provides an illustration of AMP.

#### Application:

The federal government currently uses AMP to calculate rebates due in the Medicaid Outpatient Prescription Drug Rebate Program. "Rebates are calculated separately for generic drugs and brand name drugs. The rebate for brand name drugs is the greater of 15.1 percent of AMP per unit or the difference between AMP and the manufacturer's 'Best Price' (BP - defined on page 6). In an effort to restrain drug price inflation, the rebate calculation includes an additional rebate on any drug whose price increases at a rate faster than the Consumer Price Index - Urban (CPI-U)."<sup>4</sup>

#### How Calculated:

AMP is computed quarterly by the individual drug manufacturers by dividing their total retail sales dollar value for each drug type and strength by the number of units sold.<sup>5</sup> To view a formula for calculating the Unit Rebate Amount (URA), see Appendix C (page 14).

#### Distribution Level:

Appendix B (page 13) lists the channels of drug distribution. AMP is listed at the "Manufacturers," "Wholesalers" and "Retailers (Pharmacies)" levels.

<sup>3</sup> Medicaid Drug Rebates: Improvements Needed in the Health Care Financing Administration's Procedures to Implement the Medicaid Drug Rebate Program (A-06-91-00102), Apr 92.

<sup>4</sup> Cost Containment of Medicaid HIV/AIDS Drug Expenditures (OEI-05-99-00611), Jul 01.

<sup>5</sup> Elimination of the Weighted Average Manufacturer Price Provisions of the Medicaid Outpatient Prescription Drug Rebate Program (A-06-93-00070), Dec 93.





## A Guide to Understanding Common Prescription Drug Pricing Terms

### Average Wholesale Price (AWP)

#### Definition:

AWP is the price assigned to a drug and is listed in the *Red Book*<sup>6</sup>, *First DataBank*<sup>7</sup> or *Medispan*.<sup>8</sup> AWP operates as a suggested list price, and is typically not what is paid as buyers may negotiate lower prices through the inclusion of discounts, rebates or free goods.<sup>9</sup> Appendix A (page 12) lists AWP in relation to all other prices. Appendix F (page 19) also provides an illustration of AWP.

#### Application:

AWP is the most commonly used price index in pharmaceutical transactions. The State Medicaid Agencies use AWP to calculate payments to retail pharmacies for providing drug products to Medicaid patients. AWP has recently come under significant scrutiny to determine its appropriateness as a mechanism for prescription drug reimbursement.<sup>10</sup> AWP is also used in Medicare programs for calculating the cost of drug products administered in a physician's office. Prescription benefit managers (PBMs), insurance carriers, and other managed care organizations (MCOs) use AWP to calculate payments to retail pharmacies for providing drug products to patients. Pharmacies often use AWP as a cost basis for pricing prescriptions to patients, the Retail or Usual and Customary Price (U & C, defined on page 10).

#### How Calculated:

According to the *Red Book*<sup>6</sup>, AWP pricing information is "based on data obtained from manufacturers, distributors and other suppliers."<sup>11</sup> There are no requirements or conventions that AWP reflect the price of any actual sale of drugs by a manufacturer, nor is it defined in law or regulations.<sup>12</sup>

#### Distribution Level:

Appendix B (page 13) lists the channels of drug distribution. AWP is listed at the "Manufacturers" and "Wholesalers" levels.

<sup>6</sup> The *Red Book* is published by Thomson Medical Economics.

<sup>7</sup> *First DataBank* is a provider of electronic drug information.

<sup>8</sup> *Medispan* is a product of Facts and Comparisons, a division of Lippincott Williams & Wilkins, Inc.

<sup>9</sup> Cost Containment of Medicaid HIV/AIDS Drug Expenditures (OEI-05-99-00611), Jul 01.

<sup>10</sup> Average Wholesale Price for Prescription Drugs: Is There a More Appropriate Pricing Mechanism?, NHPF Issue Brief, No. 775, Jun 02.

<sup>11</sup> Medical Economics Staff, *Red Book* 106<sup>th</sup> ed. (Montvale, NJ: Thomson Medical Economics, 2002), 169.

<sup>12</sup> Average Wholesale Price for Prescription Drugs: Is There a More Appropriate Pricing Mechanism?, NHPF Issue Brief, No. 775, Jun 02.



## *A Guide to Understanding Common Prescription Drug Pricing Terms*

### **Best Price (BP)**

#### **Definition:**

BP is defined as the lowest price available from the manufacturer to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding: (1) any prices charged to the Indian Health Service, the Department of Veteran Affairs, the Department of Defense, the Public Health Service (PHS), and PHS covered entities; (2) any prices charged under the Federal Supply Schedule; (3) any prices used under state pharmaceutical assistance program prices; and (4) any depot and single award contract prices.<sup>13</sup> The drug manufacturers provide this information.<sup>14</sup> Appendix A (page 12) lists BP in relation to the Average Wholesale Price (AWP – defined on page 5). Appendix E (page 18) also provides an illustration of Best Price.

#### **Application:**

BP is the lowest available price for a drug from the manufacturer to any purchaser with the exception of Federal agencies and State pharmaceutical assistance programs. Best Price is also used in the calculation of Medicaid rebates due in the Medicaid Outpatient Drug Rebate Program. The rebate for brand name drugs is the greater of 15.1 percent of the Average Manufacturer Price (AMP – defined on page 4) per unit or the difference between the AMP and the manufacturer's "Best Price." Rebate = 15.1% of (AMP) or (AMP - BP).

#### **How Calculated:**

The manufacturers report a drug's Best Price to the government. It is determined to be the lowest price available in the market. Each manufacturer provides this information upon review of their sale records for each drug.

Note: Best Price information is not available to the public. To view a formula for calculating the Unit Rebate Amount (URA), see Appendix C (page 14).

#### **Distribution Level:**

Appendix B (page 13) lists the channels of drug distribution. Best Price is listed at the "Manufacturers" level.

<sup>13</sup> Section 1927(c)(1)(C) of the Social Security Act

<sup>14</sup> Cost Containment of Medicaid HIV/AIDS Drug Expenditures (OEI-05-99-00611), Jul 01.



## *A Guide to Understanding Common Prescription Drug Pricing Terms*

### **Estimated Acquisition Cost (EAC)**

#### **Definition:**

EAC is a State Medicaid Agency's best estimate of the price generally paid by pharmacies for a drug.<sup>15</sup> This figure is meant to represent a calculation across all pharmacies of Actual Acquisition Cost (AAC - *defined on page 3*). Appendix A (*page 12*) lists EAC in relation to the Average Wholesale Price (AWP - *defined on page 5*). Appendix E (*page 18*) also provides an illustration of EAC.

#### **Application:**

EAC is used in the reimbursement of drugs in the Medicaid program. If a drug is a single source (brand name) drug, or a generic drug for which an upper limit amount (*see Federal Upper Limit Price - page 8*) has not been established, then the reimbursement is the lower of the pharmacist's Usual and Customary (U & C - *defined on page 10*) charge to the general public or EAC plus a reasonable dispensing fee.<sup>16</sup>

#### **How Calculated:**

The federal government does not specify any particular method for calculating EAC. States have developed their own methods for estimating acquisition cost. States typically use one of two methods: The "cost plus" method calculates the pharmacy's cost based upon the Wholesale Acquisition Cost (WAC - *defined on page 11*) plus a markup percent. The "list less" method relies upon the Average Wholesale Price (AWP - *defined on page 5*) less a discount percentage. EAC for most states is calculated by using the "list less" method.<sup>17</sup>

#### **Distribution Level:**

Appendix B (*page 13*) lists the channels of drug distribution. EAC is listed at the "Retailers (Pharmacies)" level.

<sup>15</sup> 42 CFR 447.301

<sup>16</sup> Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Washington Department of Social and Health Services (A-06-01-0006), Nov 01.

<sup>17</sup> *Ibid*



## *A Guide to Understanding Common Prescription Drug Pricing Terms*

### **Federal Upper Limit (FUL) Price**

#### **Definition:**

FUL is a Maximum Allowable Cost (MAC – *defined on page 9*) price list used in price calculations in the Medicaid program. It is also referred to as the "HCFA MAC."

#### **Application:**

See *Maximum Allowable Cost (MAC)*, page 9. FUL payment amounts have been established for over 200 drugs.<sup>18</sup>

#### **How Calculated:**

See Appendix D (*page 17*) for the formula for calculation of the FUL.

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<sup>18</sup> Medicaid's Use of Revised Average Wholesale Prices (OEI-03-01-00010), Sep 01.



## *A Guide to Understanding Common Prescription Drug Pricing Terms*

### **Maximum Allowable Cost (MAC)**

#### **Definition:**

A health plan identifies a particular drug (usually a generic product) and establishes a maximum cost per unit of medication (tablet, capsule, etc.) for that product. Each pharmacy within the plan's network then is reimbursed at that per unit price regardless of the acquisition cost of the drug. Health plans sometimes provide the list of all such drugs to their participating pharmacies, and the list is typically updated on a regular schedule (monthly, quarterly, etc.). Appendix A (page 12) lists MAC in relation to the Average Wholesale Price (AWP - defined on page 5).

#### **Application:**

MAC lists are used by health plans and prescription benefit managers (PBMs) as cost containment tools.

In addition, a MAC may be used as a marketing tool by health plans/PBMs

- To show employer groups the cost savings that can be realized with the MACs use.
- To show pharmacies the level of reimbursement, which may be higher than the MAC list of another payor.

The Medicaid program has its own MAC list; it is called the "Federal Upper Limit (FUL - defined on page 8) Price Schedule."

#### **How Calculated:**

Each health plan determines its own MAC, and uses its own formula to arrive at the MAC price. See Appendix D (page 17) for the formula for calculation of the FUL, (defined on page 8).



## *A Guide to Understanding Common Prescription Drug Pricing Terms*

### **Retail or Usual and Customary (U & C) Price**

#### **Definition:**

U & C is defined as the pharmacy's selling price to individual consumers. The price includes the cost of the drug and the pharmacy's mark-up.<sup>19</sup> The mark-up includes allowances for business operating costs, e.g. rent, utilities, employee wages/benefits, etc., and dispensing services. Appendix A (page 12) lists the U & C in relation to the Average Wholesale Price (AWP - defined on page 5). Appendix E (page 18) also provides an illustration of U & C.

#### **Application:**

U & C is also referred to as the "cash" price for the prescription.

#### **How Calculated:**

U & C is set by each individual pharmacy.

#### **Distribution Level:**

Appendix B (page 13) lists the channels of drug distribution. U & C Price is listed at the "Retailers (Pharmacies)" and "Consumer" levels.

<sup>19</sup> Prescription Drug Trends -- A Chartbook, The Henry J. Kaiser Family Foundation, Jul 2000.



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### **Wholesale Acquisition Cost (WAC)**

#### **Definition:**

WAC is the cost at which wholesalers purchase drug products from the manufacturer. This price is defined as the "list price established by manufacturers for sales to wholesalers."<sup>20</sup> The drug manufacturers provide this information. WAC, like the Average Wholesale Price (AWP – defined on page 5), is a suggested price, and is typically not what is paid.<sup>21</sup> Appendix A (page 12) lists the WAC in relation to the AWP (defined on page 5). Appendix E (page 18) also provides an illustration of WAC.

#### **Application:**

WAC is used in pharmaceutical company rebate contracts. The pharmaceutical manufacturer generally calculates the drug product rebates based on the WAC price.

#### **How Calculated:**

WAC is a proprietary price set by the pharmaceutical manufacturers. Each manufacturer assigns its own price using its own formula. *First DataBank*<sup>22</sup> and *Medispan*<sup>23</sup> report WAC prices in their drug information databases, and they are also listed in the *Red Book*.<sup>24</sup>

#### **Distribution Level:**

Appendix B (page 13) lists the channels of drug distribution. WAC is listed at the "Manufacturers" and "Wholesalers" levels.

<sup>20</sup> Cost Containment of Medicaid HIV/AIDS Drug Expenditures (OEI-05-99-00611), Jul 01.

<sup>21</sup> Ibid

<sup>22</sup> *First DataBank* is a provider of electronic drug information.

<sup>23</sup> *Medispan* is a product of Facts and Comparisons, a division of Lippincott Williams & Wilkins, Inc.

<sup>24</sup> The *Red Book* is published by Thomson Medical Economics.



## A Guide to Understanding Common Prescription Drug Pricing Terms

### Appendix A

#### Drug Price Example:

The tables below show the relationship of each price to the Average Wholesale Price (AWP). In the brand name drug example, the AWP for the drug is \$1.00 per tablet. In the generic drug example, the AWP for the generic drug is \$0.50 (generic drugs are usually less expensive than the corresponding brand name product). All prices are illustrative, and are not indicative of any one brand or generic drug.

**Note:**

Prices listed are per tablet.

Price Description - Brand Name drug	Example Price	Percent of AWP
Average Wholesale Price (AWP - page 5)	\$1.00	100%
Actual Acquisition Cost (AAC - page 3)	\$0.82	82%
Average Manufacturer's Price (AMP - page 4)	\$0.78	78%
Best Price (BP - page 6)	\$0.75	75%
Estimated Acquisition Cost (EAC - page 7)	\$0.84	84%
Maximum Allowable Cost (MAC - page 9)	\$0.25*	25%
Federal Upper Limit (FUL - page 8)	\$0.28*	28%
Usual and Customary Price (U & C - page 10)	\$1.20	120%
Wholesale Acquisition Cost (WAC - page 11)	\$0.80	80%

Price Description - Generic drug	Example Price	Percent of AWP
Average Wholesale Price (AWP - page 5)	\$0.50	100%
Actual Acquisition Cost (AAC - page 3)	\$0.20	40%
Average Manufacturer's Price (AMP - page 4)	\$0.18	18%
Best Price (BP - page 6)	\$0.15	30%
Estimated Acquisition Cost (EAC - page 7)	\$0.30	60%
Maximum Allowable Cost (MAC - page 9)	\$0.25	50%
Federal Upper Limit (FUL - page 8)	\$0.28	56%
Usual and Customary Price (U & C - page 10)	\$0.60	120%
Wholesale Acquisition Cost (WAC - page 11)	\$0.15	30%

\* A Maximum Allowable Cost (MAC) or Federal Upper Limit (FUL) price would be assigned, only if generic equivalent products to the brand name drug are available. If no generic drug is available, neither a MAC nor a FUL price would be assigned.





## A Guide to Understanding Common Prescription Drug Pricing Terms

### Appendix B

#### Channel of Distribution Levels and Price Terminology for Pharmaceuticals<sup>25</sup>

The levels of the "channel of distribution" for pharmaceuticals include manufacturers, wholesalers, retailers and consumers.\* Buying and selling occurs at each level in the channel of distribution, with specific terms applied to costs or prices at each level. In some cases, different terms used at different levels can refer to the same dollar amount.

##### Manufacturers

Manufacturers (both "major pharmaceutical firms," which emphasize research and brand name drugs, and "generic pharmaceutical firms," which focus on generic drugs) produce and market prescription and nonprescription drug products. They distribute their products predominantly through drug wholesalers, but also sell directly to individual pharmacies, pharmacy chains, hospitals and others.

*Their selling price* (to wholesalers, primarily) = Average Manufacturer Price (AMP).<sup>\*\*</sup> (Manufacturers also set the Wholesale Acquisition Cost (WAC) as a suggested list price for sale to wholesalers.) *Best Price (BP)* is the manufacturer's lowest selling price to wholesalers.

##### Wholesalers

Wholesalers serve as the middlemen that distribute drug products from manufacturers to pharmacies.

*Their cost to buy drugs* (from manufacturers) = Wholesale Acquisition Cost (WAC).  
(A manufacturer's selling price (AMP) may = the Assigned Wholesale Acquisition Cost (WAC), but the AMP may be lower.)

*Their selling price* (to pharmacies) is determined using either a "cost plus" or a "list less" approach. The resulting price might be very similar using either approach:

"Cost Plus" = Wholesale Acquisition Cost (WAC) plus a markup percent.

"List Less" = Average Wholesale Price (AWP) less a discount percent.

##### Retailers (Pharmacies)

Retailers (pharmacies) dispense prescriptions to consumers and provide professional pharmacist services.

*Their cost to buy drugs* (from wholesalers) = Actual Acquisition Cost (AAC). Sometimes pharmacies buy drugs directly from manufacturers; in that case, AAC = AMP. The Medicaid program uses Estimated Acquisition Cost (EAC) as their best estimate of AAC.

*Their selling price* (to consumers):

To Uninsured and Indemnity-Insured Consumers = The "Usual & Customary" (U & C) retail price which includes the cost of the drug plus the pharmacy's markup.

To Other Insured Consumers ("Service Benefit" Insurance Coverage) = The insurer's payment formula, typically including its determination of the cost of the drug dispensed ("ingredient cost") plus what it allows for a professional dispensing fee. The pharmacy submits a claim to the insurer equal to the formula-based price less the consumer's cost-sharing amount (the copayment or coinsurance).

##### Consumer

*Their cost to buy drugs* (from pharmacies):

If Uninsured = U & C price. (Customers with Indemnity Insurance will pay U & C price and are reimbursed that amount less any cost sharing.)

If Insured = Copayment or coinsurance amount.

##### Notes

\* Insurers are not considered participants in the channel of distribution because they are not involved in the physical distribution of drugs, though they do affect channel participants through their payment and drug use policies.

\*\* Pharmaceutical manufacturers negotiate rebates with insurers and health plans. These rebates ultimately lower the overall cost of drug program expenditures, but do not affect transaction prices (AMP). Rebates are "after market" arrangements that occur after and separately from the sales transaction.

<sup>25</sup> Adapted from: Prescription Drug Trends – A Chartbook, The Henry J. Kaiser Family Foundation, Jul 2000.



## A Guide to Understanding Common Prescription Drug Pricing Terms

### Appendix C

The Unit Rebate Amount (URA) is the amount that pharmaceutical manufacturers must reimburse the federal government for the cost of drugs used in the Medicaid program. To calculate the rebate, the following formula is used:<sup>26</sup>

"The URA calculation is performed in two ways, and **only two ways**.

1. If a product is in the category of "N" (non-innovator, multiple source), the URA is **11% of AMP** (prior to 01-01-94, it was 10%).
2. If the category is "S" (Single source) or "I" (Innovator, multiple source), the URA is calculated by using the quarterly AMP and BP, Baseline AMP and CPI-U values from the month prior to Market Date and month prior to the affected quarter. The "S"/"I" calculation is the same today as it was at the start of the program. The difference is in **WHERE THE VALUES COME FROM AND WHAT VALUES ARE USED (OR, NOT USED, AS IN THE "CAP" VALUES)!!** Based on the Market Date, there are different sets of Baseline values to use for the CPI-U Creep calculation. (See "Differences" page below.)

**NOTE:** Percentages applied to the AMP are set by law.

The URA calculation for "S" and "I" drugs is broken into two steps: the "Basic" Rebate calculation and the "Additional" Rebate calculation.

**STEP 1 - The Basic rebate** is equal to **THE GREATER OF :**  
1993 AMP X the Basic rebate % (e.g., for 1995, % was 15.2)

**OR**

b) AMP - BP

**NOTE:** For 1991, there was a CAP applied to the Basic Rebate of 25% of AMP. For 1992, it was 50% of AMP. Beginning with first quarter, 1993, the CAP was removed.

**STEP 2 - The Additional rebate** is calculated as follows:

1994 Baseline AMP / Baseline CPI-U

b) Answer to a) X quarter CPI-U

This will give a value equal to what the AMP could be raised to based on cost of living.

c) Compare the answer to b) with quarter AMP. If this is = to or GREATER than quarter AMP, there is no additional rebate amount due. If this amount is LESS than AMP, subtract this from quarter AMP. This is the ADDITIONAL Rebate owed. ADD this to the Basic URA from step 1 above to arrive at TOTAL URA for that NDC.

<sup>26</sup> Unit Rebate Amount (URA) Calculation, Powell V, HCFA Medicaid Bureau

100 North Pitt Street  
Suite 400  
Alexandria, VA 22314  
P: 703-883-8416  
F: 703-883-8417  
800-827-7627



## *A Guide to Understanding Common Prescription Drug Pricing Terms*

### **Appendix C (cont'd)**

Some examples may make the process for "S" and "I" rebate calculations more understandable. Let's look at the following:

#### Constants for Each Example

Baseline AMP = .15324

Baseline CPI-U = 149.7 ("New" Market Date = 01-01-95)

Current Quarter = 4<sup>th</sup>/95

CPI-U = 153.2 (CPI-U from September, 1995)

#### **EXAMPLE 1**

AMP = .1548

BP = .151

##### **Step 1 (Basic Rebate)**

1995 AMP X 15.2% = .0235296

b) AMP - BP = .0038

1996 is GREATER than b) thus, the Basic Rebate Amount = .0235296

##### **Step 2 (Additional Rebate)**

1997 Baseline AMP / Baseline CPI-U = .0010236

b) .0010236 X Current Quarter CPI-U = .1568155

c) answer to b) is GREATER than quarter AMP thus, the Additional Rebate = 0

**THEREFORE, THE URA = .023530 (rounded to 6 decimals)**

#### **EXAMPLE 2**

AMP = .1546

BP = .0983

##### **Step 1 (Basic Rebate)**

1998 AMP X 15.2% = .0234992

b) AMP - BP = .0563

b) is GREATER than a) thus, the Basic Rebate Amount = .0563

##### **Step 2 (Additional Rebate)**

1999 Baseline AMP / Baseline CPI-U = .0010236

b) .0010236 X Current Quarter CPI-U = .1568155

c) answer to b) is GREATER than quarter AMP thus, the Additional Rebate = 0

**THEREFORE, THE URA = .0563**

#### **EXAMPLE 3**

AMP = .2891

BP = .2763

##### **Step 1 (Basic Rebate)**

2000 AMP X 15.2% = .0439432

b) AMP - BP = .0128

2001 is GREATER than b) thus, the Basic Rebate Amount = .0439432

##### **Step 2 (Additional Rebate)**

2002 Baseline AMP / Baseline CPI-U = .0010236

b) .0010236 X Current Quarter CPI-U = .1568155

c) answer to b) is LESS than AMP thus, the additional rebate = .1322845

((AMP) .2891 - [b]) .1568155)

**THEREFORE, URA = .0439432 + .1322845 = .176228 (rounded to 6 decimals)**



## *A Guide to Understanding Common Prescription Drug Pricing Terms*

### **Appendix C (cont'd)**

#### **THE DIFFERENCES - WHAT? WHERE? WHEN? HOW? AND WHY?**

Based on the **Market Date**, there are different sets of Baseline values to use for the CPI-U Creep calculation. They are as follows:

2003 Market Date = or less than 09-30-90

For ALL quarters from 1-91 thru the present, Baseline AMP = calculated AMP for quarter 3-90 and reported with original Baseline data. Baseline CPI-U = 132.7, which is the CPI-U value for September, 1990.

2004 Market Date greater than 09-30-90 and less than 10-01-93

2005 For all quarters from 1-91 thru 3-93, Baseline AMP = AMP for the first day of the first full month the product is on the market. Baseline CPI-U = CPI-U for the month preceding the first full month.

b. For all quarters from 4-93 thru the present, Baseline AMP = calculated AMP for first quarter **AFTER Market Date**. This is true regardless of whether the Market Date is first day of a quarter, last day of a quarter, or anywhere in between. Baseline CPI-U = CPI-U **for the month prior to first quarter after Market Date**.

2006 Market Date greater than 09-30-93

Baseline AMP = calculated AMP for first quarter **AFTER Market Date**.  
Baseline CPI-U = CPI-U **for the month prior to the first quarter after Market Date**.

**NOTE:** When performing calculations for 2.a., the CPI-U creep calculation **IS NOT** performed for the quarter the product comes on the market.  
When performing calculations for 2.b. or 3., the CPI-U creep calculation **IS NOT** performed for the quarter the product comes on the market **NOR** the first quarter **AFTER** the product comes on the market.

#### **Basic Rebate Percentages**

Based on the **YEAR** the calculation is performed, the Basic Rebate Percentages (AMP X yearly %) are set by law as follows:

Quarter 1/91 thru 3/92 = 12.5%

Quarter 4/92 thru 4/93 = 15.7%

Quarter 1/94 thru 4/94 = 15.4%

Quarter 1/95 thru 4/95 = 15.2%

Quarter 1/96 forward = 15.1%

Based on the **YEAR** the calculation is performed, the Basic Rebate CAP is set by law as follows:

1991 = 25% of AMP

1992 = 50% of AMP

1993 and forward = NO CAP

When performing URA calculations, replace the CAP, Basic Rebate Percentage, Baseline AMP and/or Baseline CPI-U with values based on the above scenarios, **BUT DO NOT CHANGE THE CALCULATION**



## *A Guide to Understanding Common Prescription Drug Pricing Terms*

### **Appendix D**

#### **Federal Upper Limit (FUL) price calculation<sup>27</sup>**

Multiple source drugs are eligible for inclusion in the FUL price schedule when:

- Alike formulations of the drug approved by the Food and Drug Administration (FDA) have been evaluated as therapeutically equivalent in the current edition of the publication, Approved Drug Products with Therapeutic Equivalence Evaluations; and
- At least three suppliers list the drug in a current edition of a published national drug compendium of cost information for drugs available nationally.

The FUL price is calculated as follows:

- 150 percent of the published price for the commonly listed package size in any of the above drug compendia for the least costly therapeutically equivalent drug that can be purchased by pharmacists.

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<sup>27</sup> Follow-up Review of the Pennsylvania Department of Public Welfare's Compliance with the Federal Aggregate Upper Payment Limit Requirements for Prescription Drugs (A-03-92-00602), Apr 94

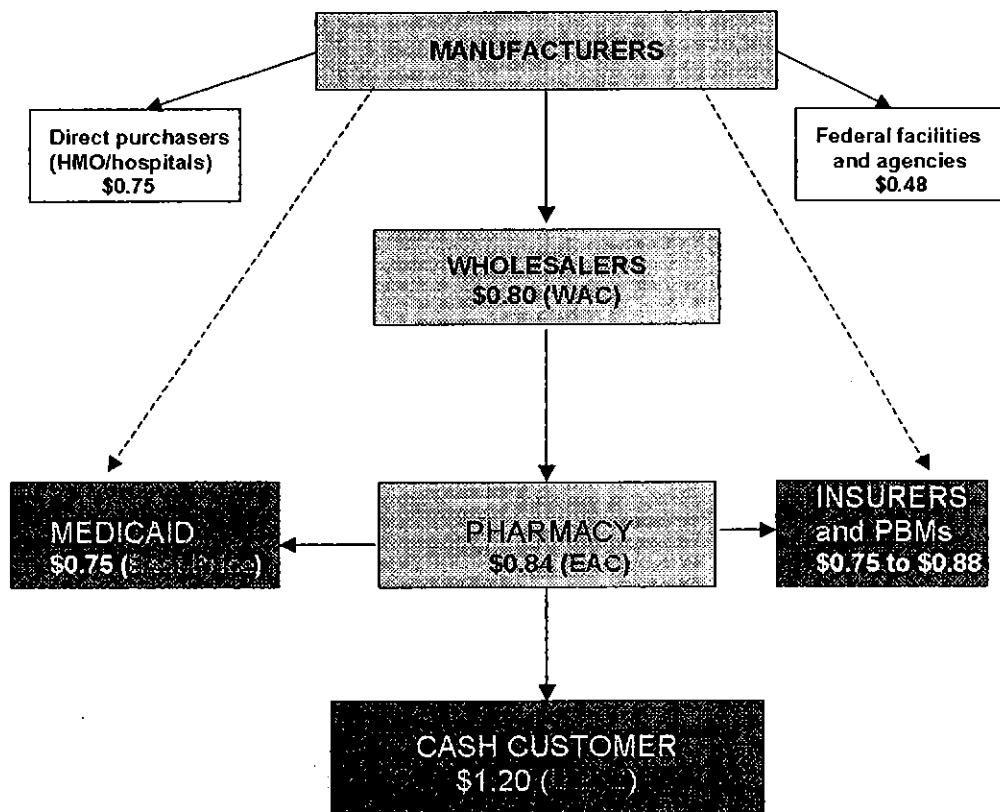


## A Guide to Understanding Common Prescription Drug Pricing Terms

### Appendix E

#### Illustration of Pricing Chains<sup>28</sup>

Prices indicate the amount typically paid for a drug with an Average Wholesale Price (AWP) of \$1.00 per tablet



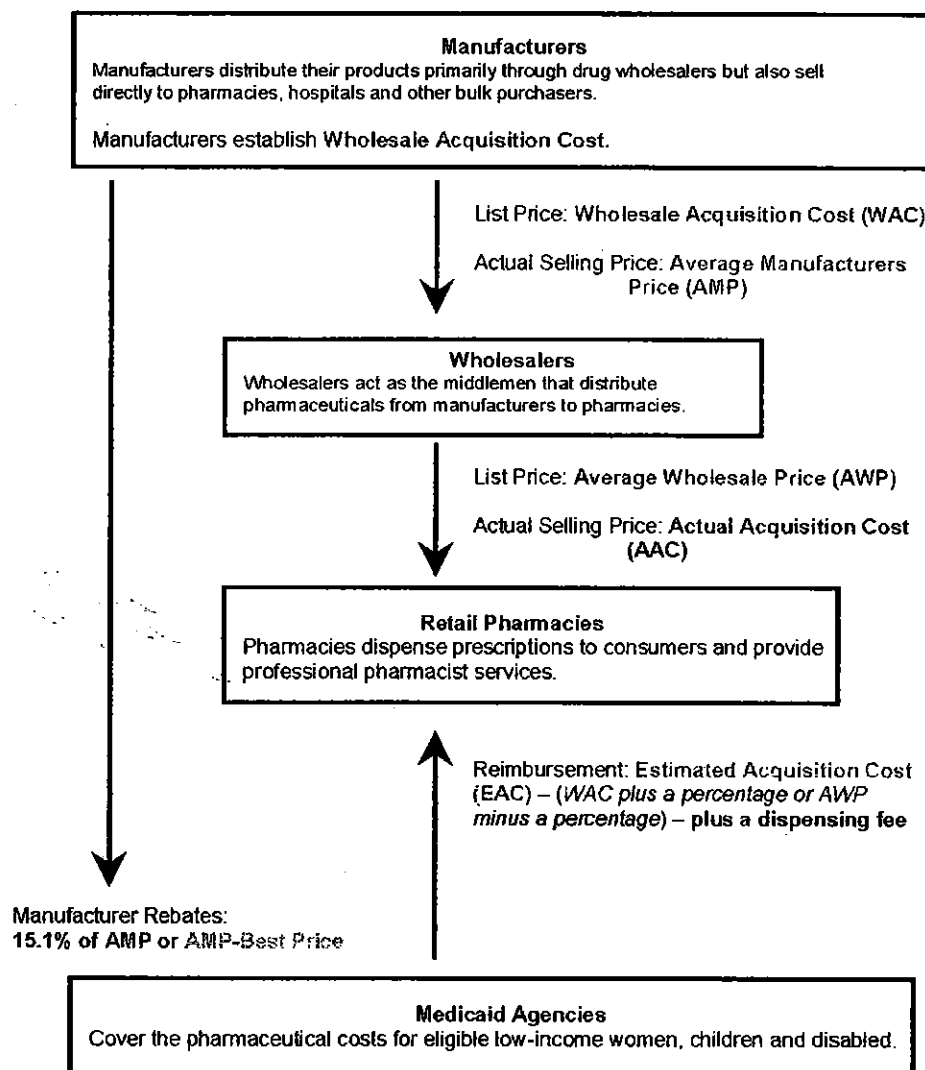
<sup>28</sup> Adapted from *The Profit in Pills: A Primer on Prescription Drug Prices* with permission of the Alliance for Retired Americans, 2001



## A Guide to Understanding Common Prescription Drug Pricing Terms

### Appendix F

#### The Pharmaceutical Industry<sup>29</sup>



<sup>29</sup> Adapted from Cost Containment of Medicaid HIV/AIDS Drug Expenditures (OEI-05-99-00611), Jul 01.

# **Exhibit 2**

**[FILED UNDER SEAL]**



# **Exhibit 3**

**[FILED UNDER SEAL]**

# **Exhibit 4**

**[FILED UNDER SEAL]**